**SODIUM CHLORIDE- sodium chloride injection**
**Henry Schein, Inc.**

---

**45764F/Revised: November 2020**

**SODIUM CHLORIDE INJECTION, USP 0.9%**

## DESCRIPTION:

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Sodium Chloride Injection, USP, 0.9% is a sterile, nonpyrogenic solution. The osmolarity is 0.300 mOsmol/mL (calculated).

Each mL contains: Sodium chloride 9 mg; Water for Injection q.s. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single dose containers. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment (pH 4.5-7.0).

Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol.

The empirical formula for sodium chloride is NaCl and the molecular weight is 58.44.

## CLINICAL PHARMACOLOGY:

Sodium chloride in water dissociates to provide sodium (Na+) and chloride (Cl—) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na+) and chloride (Cl—) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by Sodium Chloride Injection, USP, 0.9%, when used only as an isotonic vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in neonates and very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na+) plays a major role in maintaining physiologic equilibrium.

## INDICATIONS AND USAGE:

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular, or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

**PRECAUTIONS:**

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy
Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP, 0.9%. It is also not known whether Sodium Chloride Injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP, 0.9% containing additives should be given to a pregnant woman only if clearly needed.

Pediatric Use
The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Drug Interactions
Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single dose containers, discard unused portion.

**ADVERSE REACTIONS:**

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures and, if possible, retrieve and save the remainder of the unused vehicle for examination.

**OVERDOSAGE:**

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of carbohydrate, sodium chloride or fluid overload except possibly in neonates or very

small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures. (See PRECAUTIONS and ADVERSE REACTIONS).

## DOSAGE AND ADMINISTRATION:

The volume of the preparation to be used for diluting or dissolving any drug for injection, is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

## How Supplied

Sodium Chloride Injection, USP, 0.9%, preservative free, is available as follows:

| Unit of Sale | Concentration |
|---|---|
| **NDC 0409-1918-32**<br>Tub of 50 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System | 0.9% (2 mL) |
| **NDC 0409-1918-33**<br>Tub of 25 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System | 0.9% (3 mL) |
| **NDC 0409-1918-35**<br>Tub of 25 Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System | 0.9% (5 mL) |
| **NDC 0409-4888-90**<br>Tray of 10 Single-dose Plastic Fliptop Vials | 0.9% (10 mL) |
| **NDC 0409-4888-10**<br>Tray of 25 Single-dose Plastic Fliptop Vials | 0.9% (10 mL) |
| **NDC 0409-4888-20**<br>Tray of 25 Single-dose Plastic Fliptop Vials | 0.9% (20 mL) |
| **NDC 0409-4888-50**<br>Tray of 25 Single-dose Plastic Fliptop Vials | 0.9% (50 mL) |
| **NDC 0409-4888-12**<br>Tray of 25 Single-dose LifeShield® Plastic Fliptop Vials | 0.9% (10 mL) |

Preservative Free. Discard unused portion.

Use only if solution is clear and seal intact.

Store at 20º to 25ºC (68º to 77ºF) [see USP Controlled Room Temperature]

www.fresenius-kabi.com/us

45764F

Revised: November 2020

**Product repackaged by: Henry Schein, Inc., Bastian, VA 24314**

| From Original Manufacturer/Distributor's NDC and Unit of Sale | To Henry Schein Repackaged Product NDC and Unit of Sale | Total Strength/Total Volume (Concentration) per unit |
|---|---|---|
| NDC 63323-186-10<br>Unit of 25 | NDC 0404-9955-10<br>1 10 mL Single Dose vial in a bag<br>(Vial bears NDC 63323-186-01) | 0.9% |

**SAMPLE PACKAGE LABEL**

# 0.9% SODIUM CHLORIDE

0.9 %
20 ml

INJECTION, USP
Single Dose

FOR USE AS A STERILE DILUENT.
STERILE, NONPYROGENIC.
MIX THOROUGHLY AFTER DILUTION.
USE ONLY IF CLEAR AND SEAL IS INTACT AND UNDAMAGED.
PRESERVATIVE–FREE.
USE PROMPTLY. DISCARD UNUSED PORTION.

Keep out of children's reach.

STORE AT 20 TO 25C (68 to 77F).
(SEE USP CONTROLLED ROOM TEMPERATURE.)

MANUFACTURER INFORMATION
Mfr:Hospira

ORIG MFG LOT: XX–XXX–XX
NDC:0409–4888–20

RX ONLY

NDC: 0404-9954-20

ITEM# :2480808
LOT# XXXXXXXXX
EXP: mm–dd–yy

SEE MANUFACTURER'S INSERT FOR COMPLETE PRODUCT AND PRESCRIBING INFORMATION

Packaged By
Henry Schein, Inc.
80 Summit View Lane
Bastian, VA 24314

LBL : XXXXXX


# SODIUM CHLORIDE

sodium chloride injection

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0404-9955(NDC:63323-186) |
| **Route of Administration** | INTRAVENOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 9 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0404-9955-10 | 1 in 1 BAG | 01/12/2022 | |
| | | 10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a | | |

| | | | | |
|---|---|---|---|---|
| **1** | | 10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA088912 | 01/12/2022 | |

## Labeler - Henry Schein, Inc. (012430880)

Revised: 5/2024 Henry Schein, Inc.